Robert J. Schoenberg
Stephanie R. Wolfe
RIKER DANZIG SCHERER HYLAND
& PERRETTI LLP
One Speedwell Avenue
Morristown, New Jersey 07962-1981
Tel: (973) 451-8511
Email: rschoenberg@riker.com
Email: swolfe@riker.com

Don Pelto (*Pro Hac Vice pending)*
SHEPPARD MULLIN RICHTER
& HAMPTON LLP
2099 Pennsylvania Avenue, NW, Suite 100
Washington, DC 20006-6801
Tel: (202) 747-1900
Email: dpelto@sheppardmullin.com

Laura M. Burson (*Pro Hac Vice pending)*
Michelle C. Kim (*Pro Hac Vice pending)*
SHEPPARD MULLIN RICHTER
& HAMPTON LLP
333 South Hope Street, 43rd Floor
Los Angeles, CA 90071
Tel: 213.620.1780
Email: lburson@sheppardmullin.com
Email: mkim@sheppardmullin.com

Attorneys for Plaintiff
Exeltis USA Dermatology, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EXELTIS USA DERMATOLOGY, INC., a Delaware corporation, Plaintiff, v. ACELLA PHARMACEUTICALS, LLC, Defendant.	Civil Action No. _____ Hon. _____, U.S.D.J. **COMPLAINT FOR TRADE SECRET INFRINGEMENT, UNFAIR COMPETITION AND JURY DEMAND** *(Document Filed Electronically)*

Plaintiff Exeltis USA Dermatology, Inc. ("Exeltis") for its Complaint against Defendant Acella Pharmaceuticals, LLC ("Acella" or "Defendant") alleges as follows:

NATURE OF THE SUIT

1. This action seeks redress for Defendant's willful unfair competition and trade secret infringement arising from Defendant's improper acquisition, disclosure and use of Exeltis's valuable proprietary information in connection with the formulation and manufacture of Exeltis's Hydro 35® and Salvax® products (collectively, the "Proprietary Information").

2. Such acts have injured the goodwill and reputation of Exeltis and have damaged its business and, unless restrained, will continue to damage Exeltis.

JURISDICTION AND VENUE

3. The Court has original jurisdiction over this dispute, pursuant to 15 U.S.C. § 1121, 28 U.S.C. § 1331, and 28 U.S.C. § 1338(a), as the trademark and unfair competition claims stated herein arise under the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*

4. This Court further has supplemental jurisdiction over Exeltis's various state law claims set forth in this Complaint, pursuant to 28 U.S.C. §1367(a), because those claims form part of the same case or controversy as the other claims stated herein.

5. The claims alleged in this Complaint arise in the State and District of New Jersey.

6. The Court has personal jurisdiction over Defendant in this action because Defendant regularly conducts business in New Jersey, has engaged in infringing acts in New Jersey, and specifically has sold or offered to sell in New Jersey and in this judicial district the products that are the subject of this Complaint.

7. Venue is proper in this district under 28 U.S.C. §1391, as Defendant does business in this district, and upon information and belief, has sold or has offered to sell products in this district that are the subject of this suit.

THE PARTIES

8. Exeltis is a corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at One Main Street, Suite 203, Chatham, New Jersey 07928.

9. Exeltis is the successor-in-interest to Quinnova Pharmaceuticals, Inc. ("Quinnova"), a Delaware corporation, formerly located in Newtown, Pennsylvania.

10. Upon information and belief, Acella is a Delaware limited liability company, having its principal place of business at 11675 Great Oaks Way, Suite 144, Alpharetta, GA 30022.

11. Upon information and belief, Acella is the successor-in-interest, by virtue of name change, to Brookstone Pharmaceuticals, LLC ("Brookstone").

STATEMENT OF FACTS

Plaintiff Exeltis USA Dermatology, Inc. and Its Hydro 35® and Salvax® Products

12. Plaintiff Exeltis is a pharmaceutical company that has been marketing and selling and continues to market and sell various prescription-only dermatological products and other medicines throughout the United States.

13. Exeltis's reputation has been and continues to be enviable both in the trade and to the general consuming public in the United States.

14. Exeltis is well known to prescribers of dermatological products and medicines as well as to retailers, wholesalers, physicians, pharmacists, patients, and distributors in the industry in the United States.

15. Acella directly competes with Exeltis in the market for prescription-only dermatological products.

16. In 2009, Exeltis's predecessor-in-interest Quinnova started selling two prescription-only dermatological products: Hydro 35® Hydrating Topical Foam ("Hydro 35®") and Salvax® Hydrating Topical Foam ("Salvax®").

17. Hydro 35® is formulated as a keratolytic agent delivered in a water and lipid-based emollient foam containing lactic acid. Each gram of the foam contains 35% urea as the active ingredient.

18. Salvax® is formulated as a keratolytic agent delivered in a water and lipid-based

emollient foam containing salicylic acid. Each gram of the foam contains 6% salicylic acid as the active ingredient.

19. Both Quinnova and Exeltis have engaged in extensive advertising and promotion of Hydro 35® and Salvax® (the "Products") to gain goodwill and public recognition of the Products, and have spent substantial sums of money and resources to develop, advertise, and market them.

The Quinnova-Acella Relationship

20. On September 21, 2009, Quinnova and Acella (then known as Brookstone Pharmaceuticals, LLC) entered into an Authorized Generic Promotion Agreement (the "Agreement") in which Quinnova granted Acella the exclusive rights to promote, distribute and sell a generic version of Salvax®, one of Quinnova's branded dermatological products.

21. Upon information and belief, Acella's business model includes formulating alternatives or substitutes for existing branded prescription-only products and offering them for sale at lower prices.

22. The Agreement was amended twice, first on April 27, 2010, to add Quinnova's Hydro 35® prescription-only product to the list of products and again on February 23, 2011, to add a second Salvax® to be rebranded and sold under the Acella name (the "Second Amendment").

23. The Agreement contains a Confidentiality Clause (Section 6.1) pertaining to confidential information disclosed by Quinnova to Acella for the limited purpose of carrying out Acella's responsibilities under the Agreement.

24. More specifically, the Confidentiality Clause prohibits Acella from using any Quinnova Confidential Information "except pursuant to, and in order to carry out, its rights and obligations under [the] Agreement."

25. Quinnova subsequently contracted with Pharmasol Corporation ("Pharmasol"), a business located in South Easton, Massachusetts, to manufacture Hydro 35® that was thereafter sold to Acella under the Agreement.

26. In order for Pharmasol to manufacture the Hydro 35® product, Quinnova disclosed to it certain confidential and proprietary information concerning the Hydro 35® product that Quinnova, and now Exeltis, considered and continues to consider as its trade secrets, *i.e.*, the Proprietary Information.

Acella's Tortious Activities

27. Upon information and belief, at various times during 2010 and 2011, Acella visited or contacted Pharmasol purportedly to obtain quality control information concerning manufacture of Hydro 35®.

28. Upon information and belief, however, during those contacts with Pharmasol, Acella induced Pharmasol to disclose to it certain Proprietary Information concerning Hydro 35®, which Acella then used for an improper purpose.

29. The aforementioned conduct by Acella is unrelated to the purpose of the Agreement and Acella's obligations thereunder.

30. Within a matter of months after it obtained Quinnova's Proprietary Information concerning Hydro 35®, as described above, Acella failed to make a required payment, and, as a result, Quinnova notified Acella of its intent to terminate the license agreement in April 2012.

31. Upon information and belief, Acella improperly used the Proprietary Information to allow it to manufacture, or have manufactured for it, and sell a flagrant and unauthorized copycat version of Hydro 35®. A copy of the package insert for Defendant's copycat product (the "Urea Product") is attached as **Exhibit A** hereto, and a copy of the package insert for Hydro 35® is attached as **Exhibit B** hereto.

32. A comparison of the package insert for Defendant's Urea Product (**Exhibit A**) and the package insert for Exeltis's Hydro 35® (**Exhibit B**) reveals that the two products contain the same active and inactive ingredient ingredients. Both Exeltis's Hydro 35® and Defendant's Urea Product contains urea in the identical amount (35%) and both contains the exact same inactive ingredients: dimethicone, ethylparaben, glycerin, lactic acid, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, trolamine, and propellants butane and propane.

33. Upon information and belief, Acella sells its copycat Urea Product at significantly lower prices than Exeltis's Hydro 35®.

34. Upon information and belief, Acella offers for sale and has sold its lower-cost Urea Product at pharmacies in this judicial district.

35. Acella's Urea Product directly competes with Exeltis's Hydro 35® product and, by reason of Acella's marketing and sale of its product, has caused Exeltis to suffer the loss of revenues and goodwill in the market for topical dermatological products.

36. Upon information and belief, Acella's possession and use of the Proprietary Information also allowed it to manufacture, or have manufactured for it, and offer for sale and sell a flagrant and unauthorized copycat version of Salvax®. A copy of the package insert for Defendant's copycat product (the "Salicylic Acid Product") is attached as **Exhibit C** hereto, and a copy of the package insert for Salvax® is attached as **Exhibit D** hereto.

37. A comparison of the package insert for Defendant's Salicylic Acid Product (**Exhibit C**) and the package insert for Exeltis's Salvax® (**Exhibit D**) reveals that the two products contain the same active and inactive ingredients. Both Exeltis's Salvax® and Defendant's Salicylic Acid Product contains salicylic acid in the identical amount (6%) and both contains the exact same inactive ingredients: dimethicone, ethylparaben, glycerin,

methylcellulose, methylparaben, phenoxyethanol, polyoxyl 40 stearate, polysorbate 20, polysorbate 80, povidone, propylene glycol, propylparaben, purified water, sodium citrate, sodium hydroxide, stearic acid, trolamine, and propellants butane and propane.

38. Upon information and belief, Acella sells its copycat Salicylic Acid Product at significantly lower prices than Exeltis's Salvax®.

39. Upon information and belief, Acella offers for sale and has sold its lower-cost Salicylic Acid Product at pharmacies in this judicial district.

40. Acella's Salicylic Acid Product directly competes with Exeltis's Salvax® and, by reason of Acella's marketing and sale of its product, has caused Exeltis to suffer the loss of revenues and goodwill in the market for topical dermatological products.

FIRST CLAIM FOR RELIEF

Unfair Competition in Violation of 15 U.S.C. § 1125(a)

41. Each of the foregoing allegations is incorporated by reference as though fully set forth at length herein.

42. Defendant's acquisition, disclosure and use of the Proprietary Information constitutes unfair competition, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

43. The aforesaid infringement by Defendant was committed willfully, knowingly, maliciously, and in conscious disregard of Exeltis's rights.

44. Defendant's acts of unfair competition have caused great and irreparable injury to Exeltis, including but not limited to damage to its goodwill and reputation, in an amount that cannot be ascertained at this time and, unless restrained, will cause further irreparable injury to Exeltis.

45. Upon information and belief, Defendant's conduct constitutes willful and malicious infringement of Exeltis's Proprietary Information, thus rendering the present action as an "exceptional" case as that term is employed in 15 U.S.C. §1117(a).

46. Exeltis has no adequate remedy at law.

SECOND CLAIM FOR RELIEF
Unfair Competition Under N.J.S.A. 56:4-1 *et seq*.

47. Each of the foregoing allegations is incorporated by reference as though fully set forth at length herein.

48. Defendant's unauthorized acquisition, disclosure and use of the Proprietary Information in connection with the sale and advertising of its products, services and commercial activities constitutes acts of unfair competition through Defendant's appropriation for its own use of the name, reputation, and goodwill of Exeltis in violation of N.J.S.A. 56:4-1 *et seq*.

49. The aforesaid acts by Defendant were committed willfully, knowingly, maliciously, and in conscious disregard of Exeltis's rights.

50. The aforesaid acts by Defendant have caused, and unless restrained by this Court will continue to cause, immediate and irreparable injury to Exeltis's property and business.

51. Exeltis has no adequate remedy at law.

THIRD CLAIM FOR RELIEF
Common-Law Unfair Competition

52. Each of the foregoing allegations is incorporated by reference as though fully set forth at length herein.

53. The aforementioned acts of Defendant constitute unfair competition and unfair business practices contrary to the common law of the State of New Jersey.

54. The aforesaid acts by Defendant were committed willfully, knowingly, maliciously, and in conscious disregard of Exeltis's rights.

55. The aforesaid acts by Defendant have caused, and unless restrained by this Court will continue to cause, immediate and irreparable injury to Exeltis's property and business.

56. Exeltis has no adequate remedy at law.

FOURTH CLAIM FOR RELIEF

Deceptive Acts and Practices in Violation of the Common Law of the State of New Jersey

57. Each of the foregoing allegations is incorporated by reference as though fully set forth at length herein.

58. Defendant's unauthorized acquisition, disclosure and use of the Proprietary Information in connection with the sale and advertising of its products, services and commercial activities constitutes deceptive trade practices in violation of the common law of the State of New Jersey.

59. The aforesaid acts by Defendant were committed willfully, knowingly, maliciously, and in conscious disregard of Exeltis's rights.

60. The aforesaid acts by Defendant have caused, and unless restrained by this Court will continue to cause, immediate and irreparable injury to Exeltis's property and business.

61. Exeltis has no adequate remedy at law.

FIFTH CLAIM FOR RELIEF

Misappropriation Under The New Jersey Trade Secret Act, N.J.S.A. 56:15-1, *et seq.*

62. Each of the foregoing allegations is incorporated by reference as though fully set forth at length herein.

63. As discussed above, Exeltis possesses valuable Proprietary Information in connection with the formulation and manufacture of its Hydro 35® and Salvax® products.

64. The Proprietary Information, prior to unlawful disclosure by Defendant, derived independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by others in the pharmaceutical industry.

65. Exeltis implements reasonable commercial restrictions to ensure the Proprietary Information would maintain their secrecy by requiring all of those who would access the Proprietary Information be under strict express terms of confidentiality.

66. Defendant acquired the Proprietary Information with actual or imputed knowledge that such Proprietary Information was acquired through improper means by way of theft, bribery, misrepresentation, breach or inducement of a breach of an express or implied duty to maintain the secrecy of, or to limit the use or disclosure of, the Proprietary Information.

67. In addition, Defendant has disclosed and/or used the Proprietary Information without express or implied consent of Exeltis, using improper means to acquire knowledge of the Proprietary Information.

68. Alternatively, at the time of disclosure and use of the Proprietary Information, Defendant knew or had reason to know that the knowledge of the Proprietary Information was derived or acquired through improper means.

69. The aforementioned collective acts of the Defendant constitute misappropriation under the New Jersey Trade Secrets Act.

70. Defendant will, if not preliminary and permanently enjoined by the Court, continue the acts and benefits of the misappropriation, causing Exeltis immediate and irreparable harm, damage and injury.

71. As a result of the Defendant's collective actions, Exeltis has suffered injury, including irreparable injury, and damages, including lost profits, reasonable royalties, and other damages as set forth herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Exeltis USA Dermatology, Inc. respectfully requests that this Court enter judgment against Defendant Acella Pharmaceuticals, LLC, granting the following relief:

A. Judgment that Defendant has committed unfair competition in violation of 15 U.S.C. § 1125(a);

B. Judgment that Defendant has committed unfair competition in violation of N.J.S.A. 56:4-1 *et seq.*

C. Judgment that Defendant be held liable for infringing Plaintiff's trade secrets and proprietary information under N.J.S.A. 56:15-1 *et seq*. and New Jersey common law;

D. Judgment that Defendant be held liable for unfair competition and deceptive practices under New Jersey common law;

E. That Defendant be required to:

1. Deliver upon oath, to be impounded during the pendency of this action, and for destruction pursuant to judgment herein, all of Defendant's Urea Product and Salicylic Product;

2. Seek and obtain a full recall of all of Defendant's Urea Product and Salicylic Acid Product that have been sold, consigned, or placed into inventory of a wholesaler or retailer; and

3. Place all revenues generated from Defendant's sale of its Urea Product and Salicylic Acid Product, as well as all future payments from the sale of those products, in a trust account during the pendency of this action; and issue a recall and retrieve all of Defendant's Urea Product and Salicylic Acid Product that have been or is being used, advertised, marketed, offered, distributed, or sold in the marketplace;

F. That Defendant be required to file with the Court and serve on Exeltis, within 30 days after service of the Court's Order as herein prayed, a report in writing under oath stating in detail the manner and form in which Defendant has complied with the Court's Order;

G. That Defendant be required to account for and pay over to Exeltis all profits obtained by Defendant from its violations of law complained of herein;

H. That the Court grant a preliminary and permanent injunction enjoining Acella from importing, manufacturing, marketing, selling or offering for sale, its Urea Product and Salicylic Acid Product;

I. That the Court order Acella to pay compensatory damages to Exeltis in an amount to be determined at trial;

J. That the Court order Defendant to pay Exeltis's general, special, punitive and compensatory damages including, but not limited to, a trebling of Exeltis's damages pursuant to N.J.S.A. 56:4-1 *et seq.*;

K. Judgment awarding Exeltis punitive or exemplary damages in an amount appropriate to punish and to make an example of Defendant to the community;

L. That Defendant be ordered to pay prejudgment interest to Exeltis; and

M. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38, Fed. R. Civ. P., Plaintiff Exeltis USA Dermatology, Inc. hereby demands a jury trial on all issues triable of right by a jury.

Respectfully submitted,

Attorneys for Plaintiff
Exeltis USA Dermatology, Inc.

By: s/ Robert J. Schoenberg

OF COUNSEL:
Don J. Pelto
SHEPPARD MULLIN RICHTER
& HAMPTON LLP
2099 Pennsylvania Avenue, NW, Suite 100
Washington, DC 20006-6801
Tel: (202) 747-1900
Email: dpelto@sheppardmullin.com

Laura M. Burson
Michelle C. Kim
SHEPPARD MULLIN RICHTER
& HAMPTON LLP
333 South Hope Street, 43rd Floor
Los Angeles, CA 90071
Tel: 213.620.1780
Email: lburson@sheppardmullin.com
Email: mkim@sheppardmullin.com

Robert J. Schoenberg
Stephanie R. Wolfe
RIKER DANZIG SCHERER HYLAND
& PERRETTI LLP
One Speedwell Avenue
Morristown, New Jersey 07962-1981
Email: rschoenberg@riker.com
Email: swolfe@riker.com

Dated: October 13, 2015

CERTIFICATION OF NON-ARBITRABILITY

Pursuant to Local Civil Rule 201.1(d)(2), the undersigned attorneys for Plaintiff, Exeltis USA Dermatology, Inc., certify that this action is not eligible for arbitration under Local Civil Rule 201.1 because the relief sought in the Complaint primarily consists of a demand for preliminary and permanent injunctive relief, as well as damages believed to be in excess of $150,000.00, exclusive of interest, costs, and any claim for punitive damages.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for Plaintiff, Exeltis USA Dermatology, Inc., certifies that, to the best of his knowledge, the matter in controversy is not the subject of another action pending in any court or of any arbitration or administrative proceeding.

RIKER DANZIG SCHERER HYLAND
& PERRETTI LLP
Attorneys for Plaintiff
Exeltis USA Dermatology, Inc.

By s/ *Robert J. Schoenberg*
Robert J. Schoenberg

Dated: October 13, 2015

4659117v2

Exhibit A

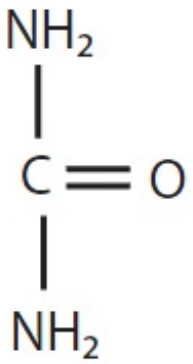
UREA HYDRATING TOPICAL - urea aerosol, foam
Acella Pharmaceuticals

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

UREA 35% HYDRATING TOPICAL FOAM (urea in a water and lipid based foam containing lactic acid, 35%) Rx Only

DESCRIPTION
Urea 35% Hydrating Topical Foam is a keratolytic emollient in a water and lipid based foam containing lactic acid which is a gentle, but potent, tissue softener for skin and nails.
Each gram of Urea 35% Hydrating Topical Foam contains Urea 35% as the active ingredient, and the following inactive ingredients: dimethicone, ethylparaben, glycerin, lactic acid, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, trolamine, and in propellants butane and propane.

CHEMICAL STRUCTURE
Urea has the following chemical structure:



CLINICAL PHARMACOLOGY
Topically applied urea dissolves the intercellular matrix of the skin which results in enhanced shedding of scaly, dry skin and thus a softening of the hyperkeratotic areas of the skin.
Urea topically applied to the nail plate has a similar effect on the intercellular matrix of the nail plate.

PHARMACOKINETICS
The mechanism of action of topically applied urea is not yet known.

INDICATIONS AND USAGE
For enzymatic debridement and promotion of normal healing of surface lesions, particularly where healing is retarded by local infection, necrotic tissue, fibrinous or purulent debris, or eschar. Topically applied urea is useful for the treatment of hyperkeratotic conditions such as dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis, keratoderma, and dry, rough skin, as well as corns and calluses and damaged, ingrown and devitalized nails.

CONTRAINDICATIONS
Known hypersensitivity to any of the listed ingredients.

WARNINGS
Urea 35% Hydrating Topical Foam is for external use only. It is not for ophthalmic, oral, anal or intravaginal use. Contact with eyes, lips, and all mucous membranes should be avoided. Urea 35% Hydrating Topical Foam should not be used by persons who have a known

hypersensitivity to urea or any of the other listed ingredients.

PRECAUTIONS
Urea 35% Hydrating Topical Foam should be used only as directed by a physician and should not be used to treat any condition other than that for which it is prescribed. If redness or irritation occurs, discontinue use and consult with a prescribing physician.

Pregnancy (Category B) – Animal reproduction studies have not been performed with topically applied urea and it is not known whether Urea 35% Hydrating Topical Foam can cause fetal harm when administered to a pregnant woman. Nevertheless, Urea 35% Hydrating Topical Foam should be used by a pregnant woman only if necessary.

Nursing Mothers – It is not known whether topically applied urea is excreted in human milk. Due to the fact that many drugs are excreted in human milk, caution should be exercised by physicians when administering Urea 35% Hydrating Topical Foam to nursing mothers.

ADVERSE REACTIONS
Transient stinging, burning, itching or irritation is possible.

DOSAGE AND ADMINISTRATION
Unless otherwise directed by a prescribing physician, Urea 35% Hydrating Topical Foam should be applied to affected area twice a day. Urea 35% Hydrating Topical Foam should be rubbed into the skin until it is completely absorbed.

HOW SUPPLIED
Urea 35% Hydrating Topical Foam is supplied in a 150 gram or 5.3 ounce aerosolized canister bearing the NDC Number 42192-115-15.

Enter section text here

NDC 42192-115-15

Urea 35% Hydrating
Topical Foam

Rx Only
Net Wt. 5.3 oz. (150 g)

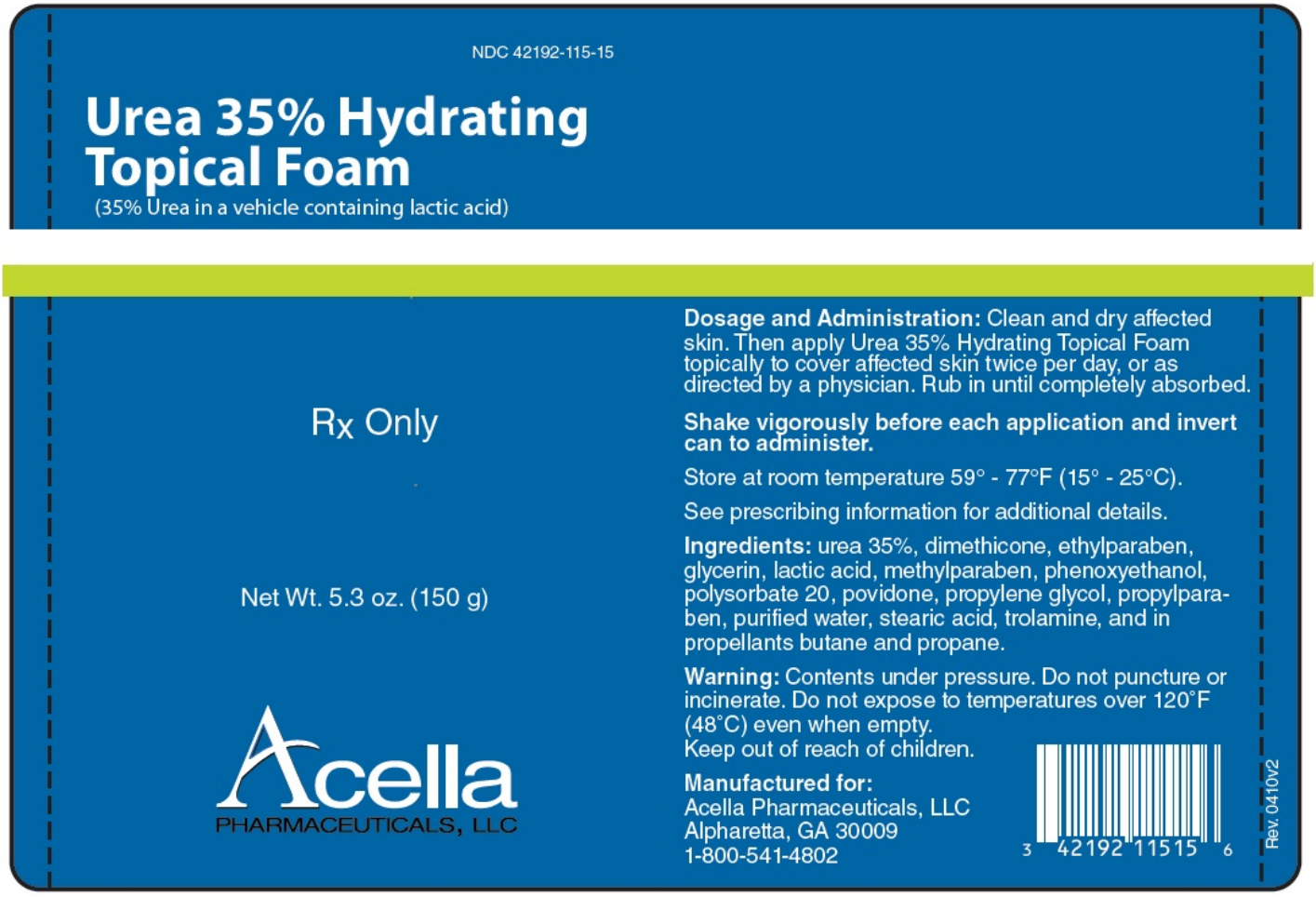
NDC 42192-115-15
Rx Only
Net Wt. 5.3 oz. (150 g)
Dosage and Administration: Clean and dry affected skin. Then apply Urea 35% Hydrating Topical Foam topically to cover affected skin twice per day, or as directed by a physician. Rub in until completely absorbed. Shake vigorously before each application and invert can to administer.

Store at room temperature 59° - 77°F (15° - 25°C).
See prescribing information for additional details.
Ingredients: urea 35%, dimethicone, ethylparaben, glycerin, lactic acid, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, trolamine, and in propellants butane and propane.

Warning: Contents under pressure. Do not puncture or incinerate. Do not expose to temperatures over 120°F (48°C) even when empty.

Keep out of reach of children.

Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30009
1-800-541-4802



UREA HYDRATING TOPICAL

urea aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-115
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	35 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-115-15	150 g in 1 CANISTER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/09/2010	

Labeler - Acella Pharmaceuticals (825380939)

Registrant - Acella Pharmaceuticals (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticlas		825380939	manufacture

Revised: 11/2010 Acella Pharmaceuticals

Exhibit B

HYDRO 35®
Hydrating Topical Foam

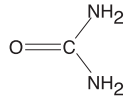
For Topical Dermatological Use Only

Rx Only – Caution: Federal Law restricts this product to sale by, or on the order of a licensed healthcare practitioner.

DESCRIPTION
HYDRO 35 Foam is a keratolytic agent delivered in a water & lipid based emollient foam containing lactic acid. This foam gently softens excess tissue to enhance removal from skin and nails, while rehydrating healthy tissue. Each gram contains 35% Urea as the active ingredient.

CHEMICAL STRUCTURE

Urea has the following chemical structure:



CLINICAL PHARMACOLOGY
Topically applied urea dissolves the intercellular matrix of the skin which results in softening of the hyperkeratotic tissue, and thus enhances shedding of scaly, dry skin. Urea topically applied to the nail plate has a similar effect on the intercellular matrix of the nail plate.

PHARMACOKINETICS
The mechanism of action of topical urea is not yet known.

INDICATIONS FOR USE
For enzymatic debridement and promotion of normal healing of surface lesions, particularly where healing is retarded by local infection, necrotic tissue, fibrinous or purulent debris, or eschar. Topically applied urea is useful for the treatment of hyperkeratotic conditions such as dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis, keratoderma, and dry, rough skin, as well as corns and calluses and damaged, ingrown and devitalized nails.

CONTRAINDICATIONS
HYDRO 35 Foam should not be used by persons who have a known hypersensitivity to urea or any of the listed ingredients.

35% UREA IN A VEHICLE CONTAINING LACTIC ACID

HYDRATING TOPICAL FOAM

HYDRO 35®

35% UREA IN A VEHICLE CONTAINING LACTIC ACID

51000020

QUINNOVA Pharmaceuticals

For Topical Dermatological Use Only

HYDRATING TOPICAL FOAM

HYDRO 35®

WARNINGS
For external use only. Not for ophthalmic, oral, anal or intravaginal use. Avoid contact with the eyes, lips, and other mucous membranes.

KEEP THIS AND OTHER MEDICATIONS OUT OF THE REACH OF CHILDREN.

Contains flammable materials. Contents under pressure. Do not puncture or incinerate. Do not expose to temperatures over 120°F (48°C) even when empty.

PRECAUTIONS
Use only as directed by a healthcare practitioner. Do not use to treat any condition other than that for which it is prescribed. If redness or irritation occurs, discontinue use and contact the prescribing healthcare practitioner.

Pregnancy (Category C) – Animal reproduction studies have not been conducted with Hydro 35 Foam. It is also not known whether Hydro 35 Foam can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hydro 35 Foam should be given to a pregnant woman only if clearly needed.

Nursing Mothers – It is not known whether topically applied urea is excreted in human milk. Due to the fact that many drugs are excreted in human milk, caution should be exercised by physicians when administering HYDRO 35 Foam to nursing mothers.

DOSAGE AND ADMINISTRATION
Apply to affected area twice a day unless otherwise directed by a prescribing healthcare practitioner. HYDRO 35 Foam should be rubbed gently into the skin until it is completely absorbed.

Follow these important directions to ensure proper foaming and maximum delivery of product:

- Shake canister vigorously before each use.
- Turn upside down (nozzle down) to dispense.
- Depress ridged portion of dispenser, as illustrated at right.

INGREDIENTS
Urea 35%, dimethicone, ethylparaben, glycerin, lactic acid, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, trolamine, and as propellants isobutane and propane.

HOW SUPPLIED
HYDRO 35 Foam is supplied in a 5.3 ounce (150g) pressurized canister bearing the NDC Number 23710-035-15 and in a 0.79 ounce (22g) pressurized canister bearing the NDC Number 23710-035-20.

Store at controlled room temperature 15° to 25°C (59° to 77°F).

U.S. Patent 5,993,830

Manufactured in the USA for
Quinnova Pharmaceuticals, LLC
Jamison, PA 18929
(877) 660-6263
www.QUINNOVA.com

Issue: December 2012, Version 1

51000020

QUINNOVA Pharmaceuticals®

Exhibit C

Salicylic Acid 6% Foam

(salicylic acid in a water and lipid based foam, 6%)

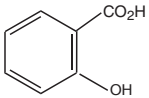
Rx Only

DESCRIPTION

Salicylic Acid 6% Foam is applied topically and used in the removal of excessive keratin in hyperkeratotic skin disorders. Each gram of Salicylic Acid 6% Foam contains salicylic acid 6% as the active ingredient, and the following inactive ingredients: dimethicone, ethylparaben, glycerin, methylcellulose, methylparaben, phenoxyethanol, polyoxyl 40 stearate, polysorbate 20, polysorbate 80, povidone, propylene glycol, propylparaben, purified water, sodium citrate, sodium hydroxide, stearic acid and trolamine and in propellants butane and propane.

CHEMICAL STRUCTURE

Salicylic acid is a 2-hydroxy derivative of benzoic acid having the following chemical structure:



CLINICAL PHARMACOLOGY

Salicylic acid has been shown to produce desquamation of the horny layer of skin while not affecting qualitative or quantitative changes in structure of the viable epidermis. The mechanism of action has been attributed to dissolution of intercellular cement substance. In a study of the percutaneous absorption of salicylic acid from Salicylic Acid 6% Foam in four patients with extensive active psoriasis, Taylor and Halprin showed that peak serum levels never exceeded 5 mg/100 mL even though more than 60% of the applied salicylic acid was absorbed. Systemic toxic reactions are usually associated with much higher serum levels (30 to 40 mg/100mL). Peak serum levels occurred within 5 hours of the topical application under occlusion. The sites were occluded for 10 hours over the entire body surface below the neck. Since salicylates are distributed in the extracellular space, patients with a contracted extracellular space due to dehydration or diuretics have higher salicylate levels than those with a normal extracellular space. (See PRECAUTIONS).

The major metabolites identified in the urine after topical administration are salicyluric acid (52%), salicylate glucuronides (42%), and free salicylic acid (6%). The urinary metabolites after percutaneous absorption differ from those after oral salicylate administration; those derived from percutaneous absorption contain more glucuronides and less salicyluric and salicylic acid. Almost 95% of a single dose of salicylate is excreted within 24 hours of its entrance into the extracellular space.

Fifty to eighty percent of salicylate is protein bound to albumin. Salicylates compete with the binding of several drugs and can modify the action of these drugs. By similar competetive mechanisms other drugs can influence the serum levels of salicylate. (See PRECAUTIONS).

PHARMACOKINETICS

The mechanism of action of topically applied salicylic acid has been attributed to the dissolution of intercellular cement substance.

INDICATIONS AND USAGE

For Dermatologic Use: Salicylic Acid 6% Foam is a topical aid in the removal of excessive keratin in hyperkeratotic skin disorders, including verrucae and the various ichthyoses, keratosis palmaris and plantaris, keratosis pilaris, pityriasis rubra pilaris and psoriasis.

For Podiatric Use: Salicylic Acid 6% Foam is a topical aid in the removal of excessive keratin on dorsal and plantar hyperkeratotic lesions.

CONTRAINDICATIONS

Salicylic Acid 6% Foam should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients. Salicylic Acid 6% Foam should not be used in children under 2 years of age.

WARNINGS

Salicylic Acid 6% Foam is for external use only. It is not for ophthalmic, oral, anal or intravaginal use. Contact with eyes, lips, broken or inflamed skin, and all mucous membranes should be avoided. Salicylic Acid 6% Foam should not be used by persons who have a known hypersensitivity to salicylic acid or any of the other listed ingredients.

Prolonged use over large areas, especially in children and those patients with significant renal or hepatic impairment could result in salicylism. Concomitant use of other drugs which may contribute to elevated serum salicylate levels should be avoided where the potential for toxicity is present. In children under 12 years of age and those patients with renal or hepatic impairment, the area to be treated should be limited and the patient monitored closely for signs of salicylate toxicity: nausea, vomiting, dizziness, loss of hearing, tinnitus, lethargy, hyperpnoea, diarrhea, psychic disturbances. In the event of salicylic acid toxicity, the use of Salicylic Acid 6% Foam should be discontinued. Fluids should be administered to promote urinary excretion. Treatment with sodium bicarbonate (oral or intravenous) should be instituted as appropriate.

Considering the potential of developing Reye's syndrome, salicylate products should not be administered to children or teenagers with varicella or influenza, unless directed by a physician.

PRECAUTIONS

Salicylic Acid 6% Foam should be used only as directed by a physician and should not be used to treat any condition other than that for which it is prescribed. Salicylic Acid 6% Foam should not be used on any skin area where inflammation or exudation is present as increased absorption may occur. If redness or irritation occurs, discontinue use and consult with prescribing physician.

Drug Interactions. (The following interactions are from a published review and include reports concerning both oral and topical salicylate administration. The relationship of these interactions to the use of Salicylic Acid 6% Foam is not known.)

I. Due to the competition of salicylate with other drugs for binding to serum albumin the following drug interactions may occur:

Drug	Description of Interaction
Tolbutamide; Sulfonylureas	Hypoglycemia potentiated
Methotrexate	Decrease tubular reabsorption; clinical toxicity from methotrexate can result
Oral Anticoagulants	Increased bleeding

II. Drugs changing salicylate levels by altering renal tubular reabsorption:

Drug	Description
Corticosteroids	Decreases plasma salicylate level; tapering doses of steroids may promote salicylism

Ammonium Sulfate	Increases plasma salicylate level

Drugs with Competitive Interactions with Salicylates

Drug	Description
Heparin	Salicylate decreases platelet adhesivesness and interferes with hemostasis in heparin-treated patients
Pyrazinamide	Inhibits pyrazinamide-induced hyperuricemia
Uricosuric Agents	Effect of probenecid, sulfinpyrazone and phenylbutazone inhibited

The following alterations of laboratory tests have been reported during salicylate therapy:

Laboratory Tests	Effect of Salicylates
Thyroid Function	Decreased PBI; increased T_3 uptake
Urinary Sugar	False negative with glucose oxidase; false positive with Clinitest with high-dose salicylate therapy (2 - 5 g qd)
5 Hydroxyindole Acetic Acid	False negative with fluorometric test
Acetone, Ketone Bodies	False positive $FeCl_3$ in Gerhardt reaction; red color persists with boiling
17-OH Corticosteroids	False reduced values with >4.8 g qd salicylate
Vanilmandelic Acid	False reduced values
Uric Acid	May increase or decrease depending on dose
Prothrombin	Decreased levels; slightly increased prothrombin time

Pregnancy (Category C) - Salicylic acid has been shown to be teratogenic in rats and monkeys. It is difficult to extrapolate from oral doses of acetylsalicylic acid used in these studies to topical administration as the oral dose to monkeys may represent 4 times the maximum daily human dose of salicylic acid (as supplied in one tube, 40 g of Salicylic Acid 6% Gel) when applied topically over a large body surface. There are no adequate and well-controlled studies in pregnant women. Salicylic Acid 6% Foam should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

Nursing Mothers - It is not known whether topically applied salicylic acid is excreted in human milk. Due to the fact that many drugs are excreted in human milk, caution should be exercised by physicians when administering Salicylic Acid 6% Foam to nursing mothers and nursing mothers should certainly not apply Salicylic Acid 6% Foam to the chest area or any other part of the body with which the nursing child's mouth is likely to come in contact.

Because of the potential for serious advers reactions in nursing infants from the mother's use of Salicylic Acid 6% Foam, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Carcinogenesis, Mutagenesis, Impairment of Fertility - No data are available concerning potential carcinogenic or reproductive effects of Salicylic Acid 6% Foam. It has been shown to lack mutagenic potential in the Ames Salmonella test.

KEEP THIS AND ALL OTHER MEDICATIONS OUT OF THE REACH OF CHILDREN.

ADVERSE REACTIONS

Transient stinging, burning, itching or irritation is possible. Peeling of the skin may increase as the salicylic acid works to loosen excess keratin. If excessive burning, stinging or peeling occurs, discontinue use and consult your physician.

DOSAGE - See WARNINGS

DOSAGE AND ADMINISTRATION

Unless otherwise directed by a prescribing physician, Salicylic Acid 6% Foam should be applied to the affected area twice a day. Salicylic Acid 6% Foam should be rubbed into the skin until it is completely absorbed.

Salicylic Acid 6% Foam should be shaken vigorously before each application and inverted to administer.

HOW SUPPLIED

Salicylic Acid 6% Foam is supplied in a 70 gram or 2.5 ounce aerosolized canister bearing the NDC Number 42192-112-70 and a 200 gram or 7.1 ounce aerolized canister bearing the NDC Number 42192-130-02 .

Store at controlled room temperature 15° - 25°C (59° - 77°F).

Contains flammable materials. Contents under pressure. Do not puncture and/or incinerate the containers. Do not expose to temperatures over 120°F (48°C) even when empty.

MANUFACTURED FOR

Acella Pharmaceuticals, LLC
Alpharetta, GA 30009
1-800-541-4802
Rev. 0311v3

Exhibit D

SALVAX®

salicylic acid, 6%

For Topical Dermatological Use Only

QUINNOVA Pharmaceuticals®

SALVAX®

salicylic acid, 6%

For Topical Dermatological Use Only

51000000

SALVAX

Hydrating Topical Foam

(salicylic acid 6% in a water and lipid based foam)

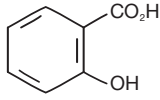
Rx Only

DESCRIPTION

SALVAX is applied topically and used in the removal of excessive keratin in hyperkeratotic skin disorders. Each gram of SALVAX contains salicylic acid 6% as the active ingredient, and the following inactive ingredients: dimethicone, ethylparaben, glycerin, methylcellulose, methylparaben, phenoxyethanol, polyoxyl 40 stearate, polysorbate 20, polysorbate 80, povidone, propylene glycol, propylparaben, purified water, sodium citrate, sodium hydroxide, stearic acid, and trolamine and as propellants isobutane and propane.

CHEMICAL STRUCTURE

Salicylic acid is the 2-hydroxy derivative of benzoic acid having the following chemical structure:



CLINICAL PHARMACOLOGY

Salicylic acid has been shown to produce desquamation of the horny layer of skin while not affecting qualitative or quantitative changes in structure of the viable epidermis. The mechanism of action has been attributed to dissolution of intercellular cement substance. In a study of the percutaneous absorption of salicylic acid from SALVAX in four patients with extensive active psoriasis, Taylor and Halprin showed that peak serum salicylate levels never exceeded 5 mg/100 ml even though more than 60% of the applied salicylic acid was absorbed. Systemic toxic reactions are usually associated with much higher serum levels (30 to 40 mg/100 ml). Peak serum levels occurred within 5 hours of the topical application under occlusion. The sites were occluded for 10 hours over the entire body surface below the neck. Since salicylates are distributed in the extracellular space, patients with a contracted extracellular space due to dehydration or diuretics have higher salicylate levels than those with a normal extracellular space. (See PRECAUTIONS).

The major metabolites identified in the urine after topical administration are salicyluric acid (52%), salicylate glucuronides (42%), and free salicylic acid (6%). The urinary metabolites after percutaneous absorption differ from those after oral salicylate administration; those derived from percutaneous absorption contain more glucuronides and less salicyluric and salicylic acid. Almost 95% of a single dose of salicylate is excreted within 24 hours of its entrance into the extracellular space.

Fifty to eighty percent of salicylate is protein bound to albumin. Salicylates compete with the binding of several drugs and can modify the action of these drugs. By similar competitive mechanisms other drugs can influence the serum levels of salicylate. (See PRECAUTIONS).

PHARMACOKINETICS

The mechanism of action of topically applied salicylic acid has been attributed to the dissolution of intercellular cement substance.

INDICATIONS AND USAGE

For dermatologic Use: SALVAX is a topical aid in the removal of excessive keratin in hyperkeratotic skin disorders, including verrucae and the various ichthyoses, keratosis palmaris and plantaris, keratosis pilaris, pityriasis rubra pilaris, and psoriasis.

For Podiatric Use: SALVAX is a topical aid in the removal of excessive keratin on dorsal and plantar hyperkeratotic lesions.

CONTRAINDICATIONS

SALVAX should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients.

WARNINGS

SALVAX is for external use only. It is not for ophthalmic, oral, anal or intravaginal use. Contact with eyes, lips, broken or inflamed skin, and all mucous membranes should be avoided. SALVAX should not be used by persons who have a known hypersensitivity to salicylic acid or any of the other listed ingredients.

Prolonged use over large areas, especially in children and those patients with significant renal or hepatic impairment could result in salicylism. Concomitant use of other drugs which may contribute to elevated serum salicylate levels should be avoided where the potential for toxicity is present. In children under 12 years of age and those patients with renal or hepatic impairment, the area to be treated should be limited and the patient monitored closely for signs of salicylate toxicity: nausea, vomiting, dizziness, loss of hearing, tinnitus, lethargy, hyperpnoea, diarrhea, psychic disturbances. In the event of salicylic acid toxicity, the use of SALVAX should be discontinued. Fluids should be administered to promote urinary excretion. Treatment with sodium bicarbonate (oral or intravenous) should be instituted as appropriate.

Considering the potential risk of developing Reye's syndrome, salicylate products should not be administered to children or teenagers with varicella or influenza, unless directed by a physician.

PRECAUTIONS

SALVAX should be used only as directed by a physician and should not be used to treat any condition other than that for which it is prescribed. SALVAX should not be used on any skin area where inflammation or exudation is present as increased absorption may occur. If redness or irritation occurs, discontinue use and consult with prescribing physician.

Drug Interactions (The following interactions are from a published review and include reports concerning both oral and topical salicylate administration. The relationship of these interactions to the use of SALVAX is not known.)

I. Due to the competition of salicylate with other drugs for binding to serum albumin the following drug interactions may occur:

Drug	Description of Interaction
Tolbutamide; Sulfonylureas	Hypoglycemia potentiated
Methotrexate	Decreases tubular reabsorption; clinical toxicity from methotrexate can result
Oral Anticoagulants	Increased bleeding

II. Drugs changing salicylate levels by altering renal tubular reabsorption:

Drug	Description
Corticosteroids	Decreases plasma salicylate level; tapering doses of steroids may promote salicylism
Ammonium Sulfate	Increases plasma salicylate level

III. Drugs with complicated interactions with salicylates:

Drug	Description
Heparin	Salicylate decreases platelet adhesiveness and interferes with hemostasis in heparin-treated patients
Pyrazinamide	Inhibits pyrazinamide-induced hyperuricemia
Uricosuric Agents	Effect of probenecid, sulfinpyrazone and phenylbutazone inhibited

The following alterations of laboratory tests have been reported during salicylate therapy:

Laboratory Tests	Effect of Salicylates
Thyroid Function	Decreased PBI; increased T_3 uptake
Urinary Sugar	False negative with glucose oxidase; false positive with Clinitest with high-dose salicylate therapy (2-5 g qd)
5 Hydroxyindole Acetic Acid	False negative with fluorometric test
Acetone, Ketone Bodies	False positive $FeCl_3$ in Gerhardt reaction; red color persists with boiling
17-OH corticosteroids	False reduced values with >4.8 g qd salicylate
Vanilmandelic Acid	False reduced values
Uric Acid	May increase or decrease depending on dose
Prothrombin	Decreased levels; slightly increased prothrombin time

Pregnancy (Category C)—Salicylic acid has been shown to be teratogenic in rats and monkeys. It is difficult to extrapolate from oral doses of acetylsalicylic acid used in these studies to topical administration as the oral dose to monkeys may represent 4 times the maximum daily human dose of salicylic acid when applied topically over a large body surface. There are no adequate and well-controlled studies in pregnant women. SALVAX should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

Nursing Mothers—It is not known whether topically applied salicylic acid is excreted in human milk. Due to the fact that many drugs are excreted in human milk, caution should be exercised by physicians when administering SALVAX to nursing mothers and nursing mothers should certainly not apply SALVAX to the chest area or any other part of the body with which the nursing child's mouth is likely to come in contact.

Because of the potential for serious adverse reactions in nursing infants from the mother's use of SALVAX, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Carcinogenesis, Mutagenesis, Impairment of Fertility—No data are available concerning potential carcinogenic or reproductive effects of SALVAX. It has been shown to lack mutagenic potential in the Ames Salmonella test.

KEEP THIS AND ALL OTHER MEDICATIONS OUT OF THE REACH OF CHILDREN.

ADVERSE REACTIONS

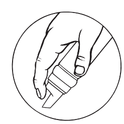
Transient stinging, burning, itching or irritation is possible. Peeling of the skin may increase as the salicylic acid works to loosen excess keratin. If excessive burning, stinging or peeling occurs, discontinue use and consult your physician.

DOSAGE AND ADMINISTRATION

Clean and dry affected skin. Then apply SALVAX topically to cover affected skin twice per day, or as directed by a physician. Rub in until completely absorbed.

Follow these important directions to ensure proper foaming and maximum delivery of product:

- **Shake canister vigorously before each use.**
- **Turn upside down (nozzle down) to dispense.**
- **Depress ridged portion of dispenser, as illustrated at right.**



HOW SUPPLIED

SALVAX is supplied in a 70 gram or 2.5 ounce aerosolized canister bearing the NDC Number 23710-006-70, a 200 gram or 7.1 ounce aerosolized canister bearing the NDC Number 23710-006-02, and a 10 gram or 0.36 ounce aerosolized canister bearing the NDC Number 23710-006-01. The 10 gram canister is a physician-dispensed sample product.

Store at controlled room temperature 15° - 25°C (59° - 77°F).

Contains flammable materials. Contents under pressure. Do not puncture or incinerate. Do not expose to temperatures over 120°F (48°C) even when empty.

U.S. Patent 5,993,830.

SALVAX is manufactured for Quinnova Pharmaceuticals LLC, Jamison, PA 18929, (877) 660-6263, www.QUINNOVA.com.

Issue Date: July 2013, REV1

QUINNOVA Pharmaceuticals ...delivering innovation® 51000000